

Remarks

This is in response to the final Office Action dated December 19, 2011 in the above-identified patent application.

Status of the Claims

- 5 Original claims 1-52 were canceled and new claims 53-80 were added during prosecution of the subject application. Claims 66 and 72-75 were previously canceled. Pending claims 53-65, 67-71, and 76-80, were subject to a Restriction Requirement, and Group I claims 53, 61, 67-68, 76-77 and 80 were elected. Withdrawn claims 54-60, 62-65, 69-71, and 78-79, as well as claim 80 were canceled by a previous amendments, and claim 67 is canceled herein. Accordingly, claims
- 10 53, 61, 68, and 76-77 remain pending for consideration.

As shown in the accompanying Listing of Claims, in addition to the cancellation of claim 67, claim 53 has now been further amended to remove the objectionable "immediate release" language, and now recites "a composition substantially free of drug."

Claim Objections

- 15 Claim 67 is objected to for its recitation of the configuration of the separation mark. Claim 67 is now canceled. Accordingly, the objection to claim 67 is moot and withdrawal of this objection is respectfully requested upon reconsideration.

Claim Rejections – 35 USC 112, 1st para.

- The prior rejection of claims 53, 61, 67-68, 76-77 is withdrawn in view of applicants' amendments to the claims and clarification. Applicants appreciate the Examiner's careful
- 20 consideration of these claims, as amended, and withdrawal of the rejection.

Claim Rejections – 35 USC 112, 2nd para.

- Claims 53 and 61 stand rejected under 35 USC 112, 2nd para., as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the
- 25 invention. This rejection is respectfully traversed.

Claim 53 is rejected for its recitation of “immediate release” in the inactive (free of drug) segment. Applicants have removed the objected-to language from claim 53. Because this issue is now believed to be moot, applicants respectfully request reconsideration and withdrawal of the rejection.

- 5 Claim 61 stands rejected for its recitation of “quick dissolve oral or buccal release within the definition of “controlled release.” It is understood by persons of ordinary skill in the art that the term “controlled release” refers broadly to release profiles that are controlled, whether made to slow or delay the release, or to control the release by speeding up the release, as compared to release profiles that result simply by conventional dissolution of the composition in the
10 environment. Therefore, the term “controlled release” may encompass, but is not limited to:

(1) a slow-dissolving formulation, such as a sustained release (SR) or extended release (ER) formulation that “sustains” or “extends” the release rate of drug, compared to an “immediate-release” (IR) formulation which dissolves immediately when ingested;

- (2) a delayed release formulation, such as an enteric-coated formulation that delays
15 dissolution, and thus delays the release, until the dosage form passes through the acidic environment of the stomach (regardless of whether the dosage form then exhibits IR or ER properties following passage through the stomach); or

- (3) a very rapid-dissolving formulation (termed “quick-dissolve”) that begins its dissolution and release prior to entering the stomach – allowing for absorption through the
20 mucous membrane of the mouth.

Thus, applicants believe the quick-dissolve formulations are within the purview of the “controlled release” limitation of the claim. Reconsideration and withdrawal of the rejection is respectfully requested.

Response to Arguments

- 25 Applicants first address the indication in the Office Action (p. 6, last paragraph) that the distinctions set forth in the previous Reply (tablet formed using a bottom punch only) were not persuasive because the features relied upon are not recited in the claims. These features, however, are believed to be provided for in the claims by virtue of the recitation of a bottom segment, which is scored, and a top segment, which is unscored.

A scored bottom segment and an unscored top segment can only result from having a bottom punch that is embossed to form that score, and a top punch which is not embossed, thereby providing an unscored top segment. Therefore, it is not required to “read” these features into the claims from the specification, because they are expressly provided. Accordingly, the applicants’ positions regarding the anticipation and obviousness rejections, set out below, should be reconsidered in light of these express recitations.

Claim Rejections – 35 USC 102

Pending claims 53, 61, 68, and 76-77 are rejected under 35 USC 102 as being anticipated by Hess (CH 648754). This rejection is respectfully traversed.

It is asserted in the Office Action that Hess describes a scored bottom (active) layer and an unscored top layer containing placebo (inactive). Respectfully, this is not what Hess describes. Instead, Hess teaches only a top *active* layer (S1) and a bottom layer (S2), which can contain active or contain placebo (inactive). To wit, the English translation version of CH 648754, at page 3, provides:

Fig 1 shows a tablet with a single break groove, whereby like the indicated above layer S1 can have another composition than the layer S2. When breaking the tablet the layer remains S1 without fractions. With a combined preparation is z. B. the retardierte active ingredient in layer S1 and the not retardierte in layer S2. With a tablet with only (retardierten) an active ingredient the layer can be S2, **also as placebo layer present** (emphasis supplied).

Hess does not teach a dosage form wherein the top layer (S1) is inactive (placebo) and further does not describe a tablet wherein the top layer S1 is inactive and the bottom layer (S2) is active, as claimed.

Moreover, Hess describes (and shows in Figures 1-3) that only the *top* layer – not the bottom layer – is scored when a score is formed in only one layer. The only instance that a score is formed on the bottom layer is when a score is formed in both the top and bottom layers. This is not the claimed invention, which has a bottom scored segment and a top *unscored* segment. It is emphasized that the current claims expressly recite that the score is formed in the “bottom” segment and that the top segment is unscored.

In view of these distinctions, Hess does not teach or describe each and every element of, and therefore cannot anticipate, the claimed invention. Reconsideration and withdrawal of the rejection under 35 USC 102 is respectfully requested.

Claim Rejections – 35 USC 103

- 5 Claims 53, 61, 68, and 76-77 stand rejected under 35 USC 103 as being unpatentable over Hess (CH 648754) in view of Medri (US 4,789,546) and Sasmal et al. (US 2005/0026992). Applicants respectfully traverse.

- The Hess reference is distinguished from the subject invention, above, as failing to teach or suggest a tablet having a top segment, which is an inactive composition, and a bottom segment, 10 which is an active composition. Hess only describes a *bottom* segment (layer S2) having placebo (i.e., being inactive). Thus, Hess describes a tablet configured in a manner which is the complete opposite of a tablet configured according to the claimed invention.

- Moreover, Hess fails to describe a tablet wherein the bottom (active) layer is scored and the top (inactive) layer is unscored. In accordance with the subject invention, a scored bottom layer, as 15 claimed, must be formed using an embossed bottom punch and a top punch that is not embossed (resulting in a top segment that is unscored, as claimed). This bottom scoring advantageously provides a divisible tablet manufactured without certain disadvantages that were surprisingly discovered by the applicants in the development of scored bi-layer tablets.

- As Dr. David Beach attests in the attached expert declaration under 37 CFR1.132 (originally 20 submitted in the related patent application, US 10/598,315), incorporated herein by reference in its entirety, applicants have discovered *disadvantages* for a layered tablet using a tablet press having an embossed top punch to form a score in the top layer or segment of the tablet, as described by Hess. For example, it is well known and accepted in the tableting arts that layer uniformity is optimized by tamping of the first layer because tamping facilitates leveling of the 25 first layer and provides a relatively flat, level, or planar surface upon which the second layer is disposed. But, tamping the first layer using an embossed top punch as described in Hess will necessarily and disadvantageously “score” the top surface of the first (bottom) layer, forming a depression in the top surface of that layer. Subsequent layers then fill in that depression, forming an uneven or non-uniform interface between the two layers.

Hess fails to describe tamping and, in a tablet scored on only a single surface (See Fig. 1 and Example 1), erroneously teaches that the embossing can be on either punch. An embossed top punch, when used for a tamping step, will disadvantageously provide a depression in the top surface of the first (bottom) layer, leading to a non-planar interface between the layers. The non-planar interface can add surface area to the broken active layer and thereby negatively affect the dissolution rate. Clearly, the Table provided at page 3, col. 2, of Hess shows increased release times for the active in each instance for the halved tablet versus the whole tablet.

The differences resulting from a top-scored tablet versus a bottom-scored tablet are evident from the photographs provided in the Appendix presented in the attached Beach Declaration. Fig. 1 shows a top-scored tablet and clearly illustrates the depression formed in the bottom layer resulting from the embossed top punch. The interface of the layers is not flat or level and the active top layer is pushed into the upper plane of the inactive layer. In Fig. 2 of the Appendix, a tablet scored using an embossed bottom punch illustrates the advantageous flat, level interface between the bottom and top layers which allows for less surface area exposure of the active layer following tablet division.

A non-planar interface between the layers is undesired aesthetically and functionally. Functionally, the depression formed by an embossed top punch provides a larger exposed surface area for the active layer when the tablet is divided at the score, which can result in more rapid dissolution of the active. A preferred embodiment of the subject invention, as claimed, provides a tablet that is scored only on the bottom surface of the bottom segment, which minimizes the exposed surface area of the active upon tablet division.

As Dr. Beach further points out, Hess is also distinguishable from the subject invention in view of its teaching of a flat “band” around the side circumference of the “rod-shaped” tablet as shown in the accompanying drawings. The subject invention is not limited to rod-shaped tablets and does not have the flat band around the circumference of the tablet, since coating of a tablet having this banding feature may cause “twinning” – adherence of the tablets to one another during spray coating or pan coating of the tablets. Thus, Hess teaches inoperable methods of forming the described tablets and does not enable the manufacture of the tablets as described.

By forming the score in the bottom layer, applicants arrived at a tablet having certain advantages, including:

- more complete separation of the layer forming the active segment or segments; and
- 5 allowance of “tamping” step, which maintains layer uniformity and prevents extrusion or mixing of active into the inactive layer.

Providing a score in the top layer using an embossed top punch, as described by Hess, cannot provide these advantages.

10 In view of the above, applicants respectfully reiterate, and submit, that Hess does not teach or describe a tablet of the subject invention.

The Office Action further cites two secondary references to complete the obviousness rejection, namely, Medri for its description of distinguishing layers by use of different colorants, and Sasmal for its description of encapsulation of mini tablets to promote patient compliance. However, neither of the cited references of Medri or Sasmal cures the defects of Hess, described
15 above and detailed in the expert declaration of Dr. Beach.

Specifically, neither of the secondary references of Medri or Sasmal provides a teaching of a bottom active layer which is scored, and a top inactive layer that is unscored. Accordingly, applicants respectfully submit that the combination of Hess, Medri, and Sasmal would not have made obvious the subject invention, as claimed (a tablet having a scored, active bottom segment
20 and an unscored, inactive top segment). Reconsideration and withdrawal of the rejection of the claims under 35 USC 103 is respectfully requested.

Applicants believe that the pending claims are in condition for allowance and respectfully request issuance of the Notice of Allowance upon reconsideration.

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Applicants invite the Examiner to contact the undersigned at the address and/or phone number provided below, if clarification or additional information is needed on any of these matters.

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Respectfully submitted,

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